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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,471	10/13/2006	Hiroyuki Aburatani	392.1004	2970

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EXAMINER	
NATARAJAN, MEERA	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,471	ABURATANI ET AL.	
	Examiner	Art Unit	
	MEERA NATARAJAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/08/2006 and 07/17/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 29-37 are currently pending and will be examined on the merits.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 08/08/2003 and the certified copy of the 2003290704 application submitted on 02/08/2006. The effective filing date for the instant application is 08/08/2003

Information Disclosure Statement

3. The references cited in the Information Disclosure Statement (IDS) on 02/08/2006 and 07/17/2006 have been considered by the examiner.

Specification

4. The disclosure is objected to because of the following informalities: embedded hyperlink on p. 23, line 31 and 35 and p. 65, line 4. Appropriate correction is required.

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 29-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. The instant claims are drawn to a method of diagnosing cancer comprising detecting C20orf102 protein. The C20orf102 protein is described in the specification as amino acid sequence SEQ ID NO:66 and gene sequence SEQ ID NO:2 (see Specification p. 50, 1st paragraph and Table 1, p. 73, No. TEG1). However, the specification also indicates the C20orf102 protein to be detected may be any C20orf102 such as dog, cat, mouse or hamster (see p. 50, 3rd paragraph). The specification does not provide SEQ ID NOs that correspond to the species listed other than human or any identifying characteristics. The specification does not indicate the percent of sequence homology between each species or any functional characteristics. The specification provides insufficient written description to support the genus encompassed by the claim.

9. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing

date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of all the species disclosed other than human C20orf102 protein (SEQ ID NO:66). See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

10. The standard for Written Description is met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." See Enzo Biochem., Inc. v. Gen-Probe Incorporated 323 F.3d 956 (Fed. Cir. 2002). There is no description of structural features shared by these disclosed species. Without such critical identifying features, one skilled in the art would not be able to recognize other species/members of the genus of C20orf102 protein and it is unclear whether applicant was in possession of the other species disclosed at the time of filing.

11. Furthermore, the instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. A person of skill is well aware, at the time of the invention was made, that different molecules, even with sequence similarity, do not necessarily have the same function. For example, Attwood (Science 290: 471-

473, 2000) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 18: 34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

12. Therefore, the disclosed species of C20orf102, i.e., dog, cat, mouse, or hamster, are not sufficiently representative of the genus of C20orf102 protein because the disclosure fails to describe the common attributes or characteristics that identify members of the genus, known and unknown at the time the invention was made.

13. Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

14. Only human C20orf102 (SEQ ID NOs: 2 and 66), but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species disclosed are not representative of the genus because the genus can be highly variant and the other species of C20orf102 can have

different functions. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

15. Claims 29-37 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of diagnosing cancer comprising detecting *human* C20orf102 protein in a human subject (detecting SEQ ID NO:66), does not reasonably provide enablement for a method of diagnosing cancer comprising detecting other species of C20orf102 protein (i.e. dog, cat, mouse, hamster). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

16. In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

17. The claims are broadly drawn to a method of diagnosing cancer comprising detecting any species of C20orf102 protein, such as dog, cat, mouse or hamster (see p. 50 of specification, 3rd paragraph) in a subject. The instant specification only provides examples of diagnosing cancer comprising detecting *human* C20orf102 protein in a blood, serum, or plasma sample from a human. The specification does not provide guidance or teachings on diagnosing cancer by detecting the other C20orf102 protein species (dog, cat, mouse or hamster).

18. The specification does not provide teachings that the C20orf102 protein in different species would have the same characteristics or functions. Even if the percent homology between the species is high, that does not necessarily mean the protein has the same function across species. For example, Attwood (Science 290: 471-473, 2000) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 18: 34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). In addition, Donovan et al. (BMC Biology, Vol. 4:14, pp.1-21, 2006) teach a model that shows humans are susceptible to retinoblastoma following

RBl loss, but mice require both *Rb* and *p107* gene inactivation. Donovan et al. explains why humans with a defective copy of the Retinoblastoma gene RB1 are at high risk of developing cancer of the retina, or retinoblastoma, whereas mice with a similar genetic profile do not develop the cancer. Donovan et al. disclose observing compensation for the lost protein expression in mice that does not occur in humans. The above references indicate that without further experimentation, one of ordinary skill in the art could not perform a method of diagnosing cancer in other species (dog, cat, mouse or hamster) by detecting the C20orf102 protein. The instant claims are only enabled for a method of diagnosing cancer in a human by detecting human C20orf102 protein (SEQ ID NO:66).

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 29-32, 34, and 36-37 are rejected under 35 U.S.C. 102 (b) as being anticipated by Yue et al. (WO/2002/026982, published April 4, 2002, cited on IDS filed 07/17/2006).

21. The claims are drawn to a method of diagnosing cancer by detecting C20orf102 protein, which is secreted outside a cell, using an antibody

recognizing C20orf102 protein in a sample from a subject. The C20orf102 protein is described in the specification as protein sequence SEQ ID NO:66 and gene sequence SEQ ID NO:2 (see Specification p. 50, 1st paragraph and Table 1, p. 73, No. TEG1).

22. Yue et al. teach a method of diagnosing cell proliferative disorders (e.g. cancers) by detecting nucleic acid and amino acid sequences of secreted proteins. Yue et al. disclose "the invention is based on the discovery of new human secreted proteins (SECP), the polynucleotides encoding SECP, and the use of these compositions for the diagnosis, treatment or prevention of cell proliferative, autoimmune/inflammatory, cardiovascular, neurological, and developmental disorders" (see p. 31, lines 28-31). Yue et al. disclose the gene sequence for C20orf102 (SEQ ID NO:2 of the instant application) and the amino acid sequence for C20orf102 protein (SEQ ID NO:66 of the instant application) (see attached alignment). Claim 30 of Yue et al. teach a diagnostic assay comprising combining a biological sample with an antibody which specifically binds to a SECP polypeptide and detecting the complex, wherein the presence of the complex correlates with the presence of the SECP polypeptide in the biological sample (see also p. 59, lines 5-6). Yue et al. disclose "sequences encoding SECP may be used for the diagnosis of disorders associated with expression of SECP" (see p. 60 lines 10-11). Yue et al. disclose several cancers including liver, lung, and pancreas (see p. 60-61). Yue et al. teaches each and every limitation of the claims.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. Claims 29-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yue et al. (WO/2002/026982, published April 4, 2002, cited on IDS filed 07/17/2006) in view of Ruben et al. (US Patent 7169565).

26. The claims are drawn to a method of diagnosing cancer by detecting C20orf102 protein, which is secreted outside a cell, using an antibody recognizing C20orf102 protein in a blood, serum, or plasma sample from a subject. The C20orf102 protein is described in the specification as amino acid sequence SEQ ID NO:66 and gene sequence SEQ ID NO:2 (see Specification p. 50, 1st paragraph and Table 1, p. 73, No. TEG1).

27. The teachings of Yue et al. are presented in the 102(b) rejection set forth above. Yue et al. does not teach a sample from a subject comprising blood, serum or plasma.

28. Ruben et al. teach a method of identifying polypeptides in a biological sample for the diagnosis of diseases using antibodies directed to said polypeptide. Ruben et al. disclose detecting expression levels of said polypeptides in bodily fluids such as blood serum or plasma (see column 30, lines 48-54).

29. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method taught by Yue et al. of determining the presence of C20orf102 protein using an antibody in samples such as blood, plasma or serum from a subject as taught by Ruben et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Yue et al. and Ruben et al. because Yue et al. disclose bodily fluids can be used in the method of detecting C20orf102 protein and Ruben et al. disclose bodily fluids such as blood, plasma and serum can be used in a method to detect polypeptide levels using an antibody directed to said polypeptide. Therefore, Claims 29-37 are obvious over Yue et al. in view of Ruben et al.

Conclusion

30. Claims 29-37 are rejected.

31. No Claim is allowed.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Meera Natarajan

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643